Priority

The Action states that, "Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120" as follows:

> The second application (which is called a continuing application) must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the continuing application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *In re Ahlbrecht,* 168 uspq 293 (ccpa 1971). Since a copy of the parent application was not provided, there is no way to ascertain if the disclosures of the two applications are the same, thus entitling applicant to priority.

The Action further states, "Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the United Kingdom on August 14, 1998. It is noted, however, that applicant has not filed a certified copy of the UK application as required by 35 U.S.C. 119(b)."

The Action further states, "If applicant wishes to obtain the benefits of a foreign filing date under 35 U.S.C. 119(a)-(d), applicant should also file a claim for such priority as required by 35 U.S.C. 119(b)."

In response to the Examiner's requests, a certified copy of the UK application is submitted herewith. Additionally, a claim for priority as required by 35 U.S.C. 119(b) is submitted herewith.

Specification

The Action states, "This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required."

An abstract has been added to the specification. The abstract is present in the International Application No. PCT/GB99/02685 from which this application claims priority and was present on the first page of the originally filed document in the instant application.

Claim Rejections - 35 USC § 112

The Action states that, "Claims 10, 12, 14-16, 19-24, 27, and 29 are rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention."

The Action states that, "A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. In the present instance, claim 10 recites the broad recitation of a filter thickness of 200-1000μm, and the claim also recites 400-800μm and 600μm, which are the narrower statements of the range/limitation."

Claim 10 has been amended to delete the text, "preferable 400-800μm, more preferably 600μm."

The Action further states, "A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. In the present instance, claim 12 recites the broad recitation of a retention size of 5-100μm, and the claim also recites 8-60μm and 10-40μm which are the narrower statements of the range/limitation.

Claim 12 has been amended to delete the text, ", preferably 8-60μm, more preferably 10-40μm".

The Action further states, "Claims 14 and 15 are rejected for the recitation of the term "capable". It is unclear if the reagents of claim 14 generate a signal or not, just as it is unclear if the antibodies of claim 15 bind spermatozoa.

Claim 14 has been amended to claim that, "a reagent or a combination of reagents [which] is/are adapted to directly or indirectly [capable of generating] generate a visual signal on interaction with spermatozoa [is/are] located in the spermatozoa detection means."

Claim 15 has been amended to claim that, "the reagent or combination of reagents include antibodies that detect an antigen present on spermatozoa and are [capable of binding] adapted to bind spermatozoa."

The Action further states, "Claim 16 is rejected for the recitation of "can be" for the same reason as applied to "capable" in claims 14 and 15. Applicant should also correct the spelling of "immobilized".

Claim 16 has been amended to claim that, "spermatozoa, when [immobilised] immobilized by the antibodies, [can be] is visually [detected] detectible using a visually detectable reagent which binds to spermatozoa."

The Action further states, "Claim 19 is rejected as vague and indefinite for the recitation of "capable" for reasons previously discussed."

Claim 19 has been amended to claim that, "said pick-up zone comprising a reagent or combination of reagents which is/are [capable of binding] adapted to bind to spermatozoa and being transported therewith to a detection area of the spermatozoa detection means".

The Action further states, "Applicant should correct the spelling of "labelled" in claims 21 and 22."

Claims 21 and 22 have been amended per the Examiner's suggestion.

The Action further states, "Applicant should change the spelling of "recognise" in claims 23 and 24 to "recognize"."

Claims 23 and 24 have been amended per the Examiner's suggestion.

The Action further states, "Claim 27 recites the limitation "the calcium ionophore A24297" in line 12. There is insufficient antecedent basis for this limitation in the claim."

Claim 27 has been amended to claim, "wherein the lysis buffer comprises Proteinase K or [the] a calcium ionophore A24297"

The Action further states, "Claim 29 is rejected as vague and indefinite for the recitation of "capable" for reasons discussed above.

Claim 29 has been amended to claim, "wherein the means for detecting pH change is a pH indicator reagent [capable of] adapted to visually [detecting] detect a pH change."

Claim Rejections - 35 USC § 102(a); Barratt (WO 99/66331)

The Action rejects Claims 1-4, 6-10, 12-31, and 45 are rejected as being anticipated by Barratt (WO 99/66331).

The Action states, "Claims Barratt discloses an apparatus and method for separating motile spermatozoa from non-motile spermatozoa comprising a vessel having an inlet and outlet with a filter disposed therebetween. The filter, whoosh [sic] may be made of gel, foam, glass wool, or polypropylene, allows passage of motile sperm, but not the rest of the sample. The apparatus further comprises a spermatozoa detection means on the outlet side of the filter, wherein the detection means is integral to the apparatus, but may be separable. The filter of the apparatus has a thickness of 25 to 2500 μm, with a pore size of 5-100μm. The filter may be supported on either or both sides of the porous layer, by means of a plastic backing. The detection zone of the apparatus preferably comprises a combination of reagents, such as antibodies, which generate a visual signal on interaction with spermatozoa. The spermatozoa, when immobilized by the antibodies, can be detected using a detectable signal that binds to the spermatozoa. The apparatus of the invention may also comprise chemoattractant in the detection means. The invention of the reference further comprises a pick up zone comprising reagents, such as labeled antibodies, capable of binding spermatozoa and being transported to a detection area. The antibodies may be labeled with gold particles. The antibodies located in the detection area may recognize the same or different spermatozoa antigens compared to the antibodies located in the pick zone. The detection means of the device may also comprise an acrososme lysing reagent and a means for detecting pH change. The acrosome-lysing reagent is preferably lysis buffer comprising proteinase K or A23187, and the pH detection means can be a pH indicator such as bromocresol purple or a pH sensitive probe. According to the reference, the device can also comprise a spermatozoa-liquefying reagent on the filter. The reference further includes means for supplying fluid to the opposing surface of the filter means, as simply putting a sample containing spermatozoa on one side of the filter meets this limitation, as the filtered sample must pass through the filter, which would place the opposing side of the filter in contact with a liquid."

Barratt (WO 99/66331) is not a proper reference to establish a 102(a) rejection. Barrat was first described in a printed publication on December 23, 1999, the International Publication Date. Applicant's date of invention is earlier than December 23, 1999, as evidenced by the filing of parent applications, i.e., British Patent Application No. 9817795.9 on August 14, 1998 and the corresponding PCT application filed on August 13 of 1999. Applicant, therefore, respectfully requests that the Examiner determine that all claim of the instant application are allowable of Barrat.

Claim Rejection 35 USC § 102(b); Alvarez (WO 96/13225)

The Action rejects Claims 1, 3-4, 6, 12, 14-16, 19-22, 31, and 45 as being anticipated by Alvarez (WO 96/13225). The Action states, "Alvarez discloses assays, kits, and devices for determining male fertility wherein motile sperm can be isolated from a sperm-containing sample, such as semen. According to the reference, a relatively dense sperm containing sample can be contacted with a less dense fluid layer, including a first fluid layer and a porous membrane, which is mounted on a liquid reservoir. The first fluid layer may include a reagent for liquefying the semen sample. The membrane allows motile sperm to pass through while preventing flow of the sample. The membrane can be composed of any suitable biocompatible material, such as nitrocellulose or glass wool. The pore size may be around 5μm. After a certain amount of time, a sample of motile sperm is removed and introduced into a test tube holding test reagents comprising antibodies, which may be labeled with particle such as gold. A test strip containing antibodies is contacted with the solution, and then contacted with a peroxidase solution. The test strip changes color to indicate the presence of motile sperm. An inlet and outlet are inherent as they are simply interpreted as areas where the sample enters and exits the filter, respectively."

Claim 1 has been amended as follows:

> [t]he sample separation filter being effective to prevent flow of the sample therethrough, but permitting passage of motile spermatozoa therethrough when said opposed surface of said sample separation filter is placed in contact with a non-sample liquid medium and (ii) means for supplying a non-sample liquid to said opposed surface of said filter, and further comprising a spermatozoa detection means on the outlet side of the sample separation filter, and spaced therefrom, and a liquid release mechanism, wherein upon activation of the liquid release mechanism, liquid from an integral liquid supply is applied to the sample filtered end of the sample separation filter to provide liquid communication with the spermatozoa detection means.

The limitations of claim 6 have been incorporated into claim 1. Additionally, limitations associated with originally filed claims 32 and 34 have been incorporated into claim 1. Claim 6 has been canceled. The addition of the "non-sample" limitations is supported on page 4, lines 14 - 20 of the originally filed document, i.e. PCT/GB99/02685, which states:

> The kit may comprise an integral liquid supply, or an external liquid supply may be used. It will be appreciated that the liquid must be one in which motile spermatozoa remain motile for a sufficient period of time to migrate to the spermatozoa detection means, ie. the liquid is generally non-toxic to spermatozoa.

> However, the liquid may be such that is (sic) has a toxicity to spermatozoa that is sufficiently low that enough spermatozoa will successfully reach the detecting means. The liquid is preferably a buffer such as phosphate buffered saline (PBS) or Earle's Balanced Salt Solution (EBSS) as described in PCT/GB99/01929.

Alvarez does not teach "[t]he sample separation filter being effective to prevent flow of the sample therethrough, but permitting passage of motile spermatozoa therethrough when said opposed surface of said sample separation filter is placed in contact with a non-sample liquid medium and (ii) means for supplying a non-sample liquid to said opposed surface of said filter", as is claimed in independent claim 1.

In contrast, with respect to Figure 1 of Alvarez, there is no teaching that retainer 24 has an opposed surface that is placed in contact with a non-sample liquid medium. Retainer 24 has a sample-receiving surface on the outside of retainer 24, but no opposed surface that is placed in contact with a non-sample liquid medium.

Similarly, with respect to Figure 2 of Alvarez, there is no sample separation filter present. Even if second fluid layer 46' was deemed to be a sample separation filter, which applicant asserts is not appropriate, there is no teaching of a sample-receiving surface and an opposed surface of said sample separation filter that is placed in contact with a non-sample liquid medium. Instead, a second fluid layer 46' has a lower or sample-receiving surface and an upper or opposing surface that is not placed in contact with a non-sample liquid medium, but instead is exposed to air.

Finally, with respect to Figure 3 of Alvarez, there is no sample separation filter present. Even if porous membrane 60 was deemed to be a sample separation filter, which applicant asserts is not appropriate, there is no teaching of a sample-receiving surface and an opposed surface of said sample separation filter that is placed in contact with a non-sample liquid medium. Instead, porous membrane 60 has a lower or sample-receiving surface and an upper or opposing surface that is not placed in contact with a non-sample liquid medium, but instead is exposed to air.

Additionally, nowhere does Alvarez teach "a spermatozoa detection means on the outlet side of the sample separation filter, and spaced therefrom" as is claimed in amended claim 1.

For at least the above reasons, applicant asserts that amended independent claim 1 is not anticipated by Alvarez (WO 96/13225). Applicant, therefore, respectfully requests allowance of amended independent claim 1.

Regarding dependent claims 1, 3-4, 6, 12, 14-16, 19-22, and 31, each depend, at least indirectly on independent claim 1, which is submitted to be patentable for the reasons set forth above. Dependent claims 1, 3-4, 6, 12, 14-16, 19-22, and 31 are submitted to be patentable for at least this reason.

Independent method claim 45 claims the steps of, "(b) applying the sample to the first surface, and (c) applying a liquid to the second surface . . ." Additionally, claim 45 has been amended to include the steps of "(d) providing a well for containing said liquid, and [(d)](e) detecting sperm that has migrated through the filter and through said liquid." For at least the reasons set forth with respect to independent apparatus claim 1, applicant asserts that method claim 45 is not anticipated by Alvarez (WO 96/13225), and should, therefore, be allowable over the cited art.

Claim Rejections 35 USC § 102(b); Jeyendran (USPN 5,575,914)

The Action rejects Claims 1, 3-4, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Jeyendran (US Pat. 5,575,914). The Action states, "Jeyendran discloses a filter trap for removing spermatozoa of low viability and other extraneous material from a fluid and allowing high viability spermatozoa (motile) to flow through, where the motile spermatozoa can then be detected. The device of the reference comprises a conduit comprising silica glass wool as the filter material. The device has an inlet, and a filtered outlet, with the filter material disposed between the two (fig. 5). As the sample, fresh ejaculate can be used, as long as it is first allowed to fully liquefy. Since the sample is applied to a first surface of the filter means, it is inherent that the sample, upon passing through the filter, will also contact the opposing surface of the filter, thereby meeting the limitation of a means for supplying fluid to the opposing surface of the filter."

Jeyendran discloses a filter trap for separating viable and non-viable sperm, and is based on the use of glass wool of a specified density. Jeyendran does not teach that "said sample separation filter is placed in contact with a non-sample liquid medium and (ii) means for supplying a non-sample liquid to said opposed surface of said filter" as is claimed in applicant's amended claim 1. The present application teaches that motile sperm become able to migrate from a semen sample when the opposed face of the filter is wetted by a non-sample liquid medium ('activated'). In contrast, Jeyendran teaches no use of a liquid medium other than washing the glass wool 16

with 3ml portions of a suitable fluid or medium "until microscopic examination reveals that the filtrate is free of wool fibers" (Col. 7, lines 25-29).

Additionally, nowhere does Jeyendran teach "a spermatozoa detection means on the outlet side of the sample separation filter, and spaced therefrom" as is claimed in amended claim 1.

For at least the above reasons, applicant asserts that independent claim 1 is not anticipated by USPN 5,575,914 to Jeyendran. Applicant, therefore, respectfully requests allowance of amended independent claim 1.

Regarding dependent claims 3 and 4, each depend, at least indirectly on amended independent claim 1, which is submitted to be patentable for the reasons set forth above. Dependent claims 3 and 4, are, therefore submitted to be patentable for at least this reason.

Independent method claim 45 claims the steps of, "(b) applying the sample to the first surface, and (c) applying a liquid to the second surface . . ." Additionally, claim 45 has been amended to include the steps of "(d) providing a well for containing said liquid, and [(d)](e) detecting sperm that has migrated through the filter and through said liquid."

For at least the reasons set forth, above, applicant asserts that method claim 45 is not anticipated by USPN 5,575,914 to Jeyendran, and should, therefore, be allowable over the cited art.

Claim Rejections 35 USC § 102(e); Zavos (USPN 5,976,389)

The Action rejects Claims 1 and 45 as being anticipated by Zavos (US Pat. 5,976,389). The Action states, "Zavos discloses a method and device for semen filtration comprising admixing Sephadex beads in the column of a filtering device having opening at both ends with a media. The multilayer filter will allow the passage of motile spermatozoa, which can then be recovered. The semen for use with the device must first be liquefied."

Nowhere does Zavos teach "a spermatozoa detection means on the outlet side of the sample separation filter, and spaced therefrom" as is claimed in amended claim 1. Instead, Zavos teaches that, "When hydrated with standard laboratory media, the beads expand and settle, forming a multi-layer filter" (Col. 1, lines 22-24).

For at least the above reasons, applicant asserts that independent claim 1 is not anticipated by USPN 5,976,389 to Zavos. Applicant, therefore, respectfully requests allowance of amended independent claim 1.

Claim 45 has been amended to include the steps of "(d) providing a well for containing said liquid, and [(d)](e) detecting sperm that has migrated through the filter and through said liquid." Zavos does not teach the sperm migrates through a liquid in a well, but instead teaches that spermatozoa is diluted in a media (col. 2, lines 39 and 40), placed into the Semen Filter column after removing the top stopper (col. 2, lines 54 and 55) and allowed to drip down the column and mix with the dehydrated Sephadex beads on the lower insulate disc (col. 2, lines 59 - 61).

For at least the above reasons, applicant asserts that independent method claim 45 is not anticipated by USPN 5,976,389 to Zavos. Applicant, therefore, respectfully requests allowance of amended independent claim 45.

Claim Rejections - 35 USC § 102(e); Bar-Ami et al (USPN 6,129,214)

The Action rejects Claims 1, 3 and 12 as being anticipated by Bar-Ami et al. (US Pat. 6,129,214). The Action states, "Bar Ami et al. disclose a sperm strainer system which filters motile sperm from a semen sample using a necleopore membrane, which can be made of nylon, with a pore size of 5-8 microns. The sperm sample is placed on one side of the membrane, and the motile sperm migrate through the membrane, and leave the non-motile sperm and other extraneous materials behind. The nucleopore membrane has first and second opposing surfaces, both of which will be contacted with a liquid medium, as the sample portion containing the motile sperm will contact both surfaces as it flows through the filter. An inlet and filtered outlet means are inherent in the device of the reference."

Claim 1 has been amended to add the following limitations:

> [a]nd further comprising a spermatozoa detection means on the outlet side of the sample separation filter, and spaced therefrom, and a liquid release mechanism, wherein upon activation of the liquid release mechanism, liquid from an integral liquid supply is applied to the sample filtered end of the sample separation filter to provide liquid communication with the spermatozoa detection means.

Bar-Ami does not include an integral liquid supply, nor a liquid release mechanism to release the supplied liquid to the sample filtered end of the sample separation filter; in fact, Bar-Ami teaches the opposite, as can be seen for the drawings and from the preferred embodiment. In the Bar-Ami device, a semen sample is placed onto a filter and this filter is then placed into a separate dish which already contains the "target medium". In contrast, the presently claimed device has an integral liquid supply that keeps the opposed face of the filter dry until, when desired, it is actuated and the contents are released to wet the sample filtered end of the sample separation filter.

Additionally, Bar-Ami does not teach that the "target medium" is part of a self-contained device such that it is stored prior to use in an integral liquid supply and is then released during use to wet the sample filtered end of the filter and thereby start the separation process.

For at least the above reasons, applicant asserts that independent claim 1 is not anticipated by USPN 6,129,214 to Bar-Ami et al. Applicant, therefore, respectfully requests allowance of amended independent claim 1.

Regarding dependent claims 3 and 12, each depend on amended independent claim 1, which is submitted to be patentable for the reasons set forth above. Dependent claims 3 and 12, are, therefore submitted to be patentable for at least this reason.

Claim Rejections - 35 USC § 103; Jayendran (USPN 5,575,914)

The Action rejects Claim 31 as being unpatentable over Jayendran (US Pat. 5,575,914).

The Action states that, "Jayendran teaches a semen filtration device, as discussed above. However, the reference does not teach the use of an enzyme liquefaction reagent on the surface of the filter."

The Action further states that "It would have *been prima* facie obvious to one of ordinary skill in the art at the time of the invention to use a liquefaction reagent with the advice of Jayendran. Since the device of the reference requires sperm liquefaction before filtration, placing a liquefaction reagent on the surface of the filter would save considerable time, as both functions could be carried out almost simultaneously with the same device."

Regarding dependent claim 31, claim 31 depends from amended independent claim 1, which is submitted to be patentable for the reasons set forth above. Dependent claim 31 is, therefore submitted to be patentable for at least this reason.

Conclusion

In view of the foregoing, Applicant respectfully requests the thorough reconsideration of this application and earnestly solicits an early notice of allowance.

Respectfully submitted,
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Version with markings to show changes made in response to Office Action dated 5/23/01:

In the specification:

Abstract

A kit (10) for testing male fertility comprises a vessel (12), a base unit (14), a liquid supply (16) containing liquid (18), and two filters (20,22). The first filter (20) is a sample separation filter (20) which forms a hindrance to transmission of spermatozoa. The second filter (22) of the kit is a spermatozoa detection filter (22) comprising a reagent for identifying spermatozoa. Activation of the kit is prevented until a transport medium, such as the liquid, fills a gap (24) allowing a spermatozoa to transmit to a detection zone (26). The kit may be of one-piece construction and utilizes a thin piece of filter material to separate motile from non-motile spermatozoa.

In the Claims:

1. (Amended) An apparatus for separating motile spermatozoa from non-motile spermatozoa in a liquid sample, the apparatus comprising (i) a vessel having a sample receiving inlet, a filtered sample outlet and a sample separation filter mounted therebetween, the sample separation filter having a sample-receiving surface and an opposed surface, and the sample separation filter being effective to prevent flow of the sample therethrough, but permitting passage of motile spermatozoa therethrough when said opposed surface of said sample separation filter is placed in contact with a non-sample liquid medium and (ii) means for supplying a non-sample liquid to said opposed surface of said filter, and further comprising a spermatozoa detection means on the outlet side of the sample separation filter, and spaced therefrom, and a liquid release mechanism, wherein upon activation of the liquid release mechanism, liquid from an integral liquid supply is applied to the sample filtered end of the sample separation filter to provide liquid communication with the spermatozoa detection means.

5. An apparatus according to [any preceding claim] claim 1, wherein the sample additionally comprises non-motile spermatozoa and spermatozoa with reduced motility.

7. (Amended) An apparatus according to claim [6] 1, wherein the detection means is integral with the apparatus.

8. (Amended) An apparatus according to claim [6] 1, wherein the detection means is a separable component of the apparatus for inserting into the apparatus before, during or after placing the sample separation filter in contact with the liquid medium.

10. (Twice Amended) An apparatus according to claim 9, wherein the filter has a thickness of 200-1000μm[, preferable 400-800μm, more preferably 600μm].

12. (Twice Amended) An apparatus according to claim 1, wherein the filter has a minimum particle retention size of 5-100μm[, preferably 8-60μm, more preferably 10-40μm].

14. (Twice amended) An apparatus according to claim [6] 1, wherein a reagent or a combination of reagents [which] is/are adapted to directly or indirectly [capable of generating] generate a visual signal on interaction with spermatozoa [is/are] located in the spermatozoa detection means.

15. (Amended) An apparatus according to claim 14, wherein the reagent or combination of reagents include antibodies that detect an antigen present on spermatozoa and [are capable of binding] can bind spermatozoa.

16. (Amended) An apparatus according to claim 15, wherein spermatozoa, when [immobilised] immobilized by the antibodies, [can be] are visually [detected] detectable using a visually detectable reagent which binds to spermatozoa.

17. (Twice amended) An apparatus according to claim [6] 1, wherein a spermatozoa chemoattractant is located in the spermatozoa detection means.

19. (Twice amended) An apparatus according to claim [6] 1, wherein a pick-up zone is located either in the sample separation filter or the spermatozoa detection means, said pick-up zone comprising a reagent or combination of reagents which [is/are capable of binding to] can bind spermatozoa and being transported therewith to a detection area of the spermatozoa detection means.

21. (Amended) An apparatus according to claim 20, wherein the antibodies that detect an antigen present on spermatozoa are detectably [labelled] labeled.

22. (Amended) An apparatus according to claim 21, wherein the antibodies that detect an antigent present on spermatozoa are detectably [labelled] labeled with gold particles.

23. (Twice amended) An apparatus according to claim 20, wherein the antibodies that are located in a detection area of the spermatozoà detection means [recognise] recognize a different spermatozoa antigen compared to the antibodies located in the pick-up zone.

24. (Twice amended) An apparatus according to claim 20, wherein the antibodies that are located in a detection area of the spermatozoa detection means [recognise] recognize the same spermatozoa antigen as the antibodies located in the pick-up zone.

25. (Twice amended) An apparatus according to claim [6] 1, wherein the spermatozoa detection means comprises a spermatozoa acrosome-lysing reagent and a means for detecting pH change.

27. (Amended) An apparatus according to claim 26, wherein the lysis buffer comprises Proteinase K or [the] calcium ionophore A24297.

29. (Twice amended) An apparatus according to claim 25, wherein the means for detecting pH change is a pH indicator reagent [capable of] adapted to visually [detecting] detect a pH change.

45. (Twice amended) A method of detecting the presence of motile sperm in a sample, comprising:

(a) providing a filter having first and second surfaces, the filter permitting migration of the motile sperm therethrough when a liquid is applied to the second surface, wherein the filter is the filter container within the apparatus of any of claims 1 to 31,

(b) applying the sample to the first surface,

(c) applying a liquid to the second surface, [and]

(d) providing a well for containing said liquid, and

[(d)](e)detecting sperm that has migrated through the filter and through said liquid.

52. (New) An apparatus according to claim 9, wherein the filter has a thickness of approximately 400-800μm.

53. (New) An apparatus according to claim 12, wherein the filter has a minimum particle retention size of approximately 8-60μm.

54. (New) An apparatus according to claim 12, wherein the filter has a minimum particle retention size of approximately10-40μm.

55. (New) An apparatus according to claim 2, wherein the sample additionally comprises non-motile spermatozoa and spermatozoa with reduced motility.

56. (New) An apparatus according to claim 3, wherein the sample additionally comprises non-motile spermatozoa and spermatozoa with reduced motility.